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Abstract: **OBJECTIVES:** To describe clinical effects, circumstances of occurrence, management and outcomes of cases of inadvertent administration of medications by an incorrect parenteral route. **METHODS:** Retrospective single-center consecutive review of parenteral route errors of medications, reported to our center between January 2006 and June 2010. We collected demographic data and information on medications, route and time of administration, severity of symptoms/signs, treatment, and outcome. **RESULTS:** Seventy-eight cases (68 adults, 10 children) were available for analysis. The following wrong administration routes were recorded: paravenous (51%), intravenous (33%), subcutaneous (8%), and others (8%). Medications most frequently involved were iodinated x-ray contrast media (11%) and iron infusions (9%). Twenty-eight percent of the patients were asymptomatic and 54% showed mild symptoms; moderate and severe symptoms were observed in 9% and 7.7%, respectively, and were mostly due to intravenous administration errors. There was no fatal outcome. In most symptomatic cases local non-specific treatment was performed. **CONCLUSIONS:** Enquiries concerning administration of medicines by an incorrect parenteral route were rare, and mainly involved iodinated x-ray contrast media and iron infusions. Most events occurred in adults and showed a benign clinical course. Although the majority of exposures concerned the paravenous route, the occasional severe cases were observed mainly after inadvertent intravenous administration.

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Medication wrong route administration: a poisons centre-based study

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Key words:

Iatrogenic errors; medications; poisons centre; route of administration.

Abstract

Objectives

To describe clinical effects, circumstances of occurrence, management and outcomes of cases of inadvertent administration of medications by an incorrect parenteral route.

Methods

Retrospective single-centre consecutive review of parenteral route errors of medications, reported to our centre between January 2006-June 2010. We collected demographic data and information on medications, route and time of administration, severity of symptoms/signs, treatment, and outcome.

Results

78 cases (68 adults, 10 children) were available for analysis. The following wrong administration routes were recorded: paravenous (51%), intravenous (33%), subcutaneous (8%), and others (8%). Medications most frequently involved were iodinated x-ray contrast media (11%) and iron infusions (9%). 28% of the patients were asymptomatic and 54% showed mild symptoms; moderate and severe symptoms were observed in 9% and 7.7%, respectively, and were mostly due to intravenous administration errors. There was no fatal outcome. In most symptomatic cases local nonspecific treatment was performed.

Conclusions

Enquiries concerning administration of medicines by an incorrect parenteral route were rare, and mainly involved iodinated x-ray contrast media and iron infusions. Most events occurred in adults and showed a benign clinical course. Although the majority of exposures concerned the paravenous route, the occasional severe cases were observed mainly after inadvertent intravenous administration.

1. Introduction

Administration of medications is a frequent process in health care facilities and errors may occur at different stages, including prescribing, dispensing, preparing, administering and monitoring [1-5]. Furthermore, previous studies have shown that medication errors encompass different types such as wrong medication, wrong dose, wrong time, and wrong route [6-8]. Within the latter group, parenteral administration errors are particularly relevant because of the potential risk for serious outcomes [9-11]. However, information in the literature about the circumstances and consequences of application of medicines by the wrong route is limited and mostly based on single case reports for most specialties. In contrast, in oncology, where parenteral administration of highly toxic substances is frequent, a number of publications have addressed this issue [12-14]. Some of the studies on medication errors were performed by poisons centres (PCs), which are reference centres in case of poisoning and medication-related problems and often cover a referral population in the range of some million people. PCs therefore exert also a centralizing function in collecting and documenting cases of administration errors of medications and medicinal products, and in assisting clinicians in the management of these events [9,10,15]. Furthermore, the potential reluctance of health care professionals to report such events may be mitigated by the fact that PCs are not enforcement authorities, and therefore health care providers do not have to be concerned about disciplinary actions and medico-legal liability. Nevertheless, it is possible that a substantial number of wrong route application cases remain unreported, because medical errors are a delicate issue and health professionals may be unwilling to provide information [9,16]. Furthermore, it has been suggested that PCs are more likely to be contacted in severe cases [9,10], so that mild and moderate cases may be underrepresented in analyses based on PCs data.

The aim of this study was to describe clinical effects, circumstances of occurrence (i.e. daytime and weekday of occurrence, involved hospital departments), management, and outcomes of cases of inadvertent parenteral administration of medications reported to the Swiss Toxicological Information Centre in order to improve the management in affected patients and to contribute to the prevention of these errors.

2. Methods

2.1 Data acquisition

The Swiss Toxicological Information Centre (STIC) provides nationwide free 24/7 medical advice in cases of poisoning to health professionals and the general public. The referral population is about 7.9 million people. Demographic and detailed clinical information on exposed cases including age (children defined as ≤ 16 y), sex, and weight of the patient, circumstances of poisoning, doses of all substances involved, symptoms/signs, and causality are recorded in a systematic and standardized manner by a physician trained in clinical toxicology and blinded to any study hypotheses at the time of the initial phone call. These data are prospectively entered into an in-house structured electronic database. For reports by health care professionals, the STIC collects additional specific clinical data – including complementary information on type and, if applicable, concentration of the substances involved, current history and circumstances of substance intake, observed symptoms and signs, Glasgow Coma Scale (GCS) score, electrocardiography results, therapeutic interventions and any decontamination measures performed, latency to decontamination, observed clinical course, and eventual medical complications - using a standardized report form which is sent to the treating physician. Hospital physicians are also asked to provide a discharge letter and any laboratory results, as well as the results of other examinations. This

follow-up information is then matched with the data taken during the initial call and entered into the database to complement the case files. At this stage evaluation of severity and causality is performed. Each case is then reviewed by a senior clinical toxicologist to ensure completeness and correctness of entered data before finalizing recording into the database.

2.2 Study design

We performed a retrospective single-centre consecutive review of parenteral route errors (PREs) of medications – defined as errors involving the administration of medications or medicinal products (e.g. contrast media, disinfectants, diagnostic medications) by an incorrect parenteral route and caused by a qualified medical person (medical doctor, nurse and other health care professional) – in humans (children and adults), which were reported to the STIC between January 2006 and June 2010.

2.3 Study population

Between January 2006 and June 2010 the STIC recorded a total of 121,989 human exposures to toxic substances in the PC database. Based on this population, a search for the following terms (at least one) “paravenous”, “extravasation”, “inadvertent”, “by mistake”, “instead”, “erroneous”, “by accident”, and “confusion” was performed and revealed 127 cases of parenteral wrong route administrations, fulfilling the inclusion/exclusion criteria (see below). From the 127 cases, 49 were excluded because written feedback from the treating physician was lacking, leaving 78 cases for further analysis.

2.4 Inclusion and exclusion criteria

The following criteria had to be met for reported cases to be included in the study:

- Route of administration: parenteral (i.e. intravenous, paravenous, intra-arterial, subcutaneous, intramuscular, intraperitoneal, intrathecal);
- Case description by a qualified medical person with written feedback from the treating physician with sufficient information about symptoms/signs, clinical course, and outcome;
- Good evidence for exposure (i.e. observed incorrect administration and/or characteristic local symptoms);
- High degree of causal relationship between exposure and clinical effect (for symptomatic cases): cases in which other causes for the observed symptoms and signs were excluded, or considered less likely than the PRE.

Each case was reviewed in detail and independently assessed by an expert panel including two pharmacists, a clinical toxicologist, and a clinical pharmacologist and general internist. Any disagreement in case assessment was resolved by consensus.

Exclusion criteria were:

- Administration of a medication or medicinal product to the wrong patient but by the right application route;
- Self-injection of veterinary medicines by veterinary doctor or other qualified person;
- Non-parenteral and other application routes (i.e. oral, rectal, nasal, ocular, vaginal, cutaneous, inhalational);
- Suicidal intent.

2.5 Data processing and classification

Data were extracted into a standardized Excel spreadsheet format, and categorized into age groups, medications involved (according to the Anatomic Therapeutic Chemical (ATC)

classification system [17]), routes and times of administration, and severity of symptoms and signs. The severity of symptoms was graded in accordance with the Poisoning Severity Score (PSS) developed by the European Association of Poisons Centres and Clinical Toxicologists, the WHO International Program on Chemical Safety (IPCS), and the European Commission [18]: ‘minor’, for mild, transient and spontaneously resolving symptoms/signs; ‘moderate’, if at least one pronounced or prolonged symptom/sign was recorded; ‘severe’ if at least one severe or life-threatening symptom/sign was observed, or ‘fatal’ if the administration error was the recorded cause of death.

2.6 Statistical evaluation

Statistical analysis for descriptive statistics was performed using the SPSS software package (version 18.0; SPSS Inc., Chicago, IL, USA).

2.7 Ethical approval

Informed consent from patients or ethics approval was not necessary due to the nature of the study design according to the regulations of the cantonal ethics committee Zurich.

3. Results

3.1 Patient characteristics

Demographic characteristics of the 78 patients included in the study were as follows: 68 adults (87%) with a mean age of 57.9 years (SD 19, median 58.5, range 20–89) and 10 children with a mean age of 4.1 years (SD 2.6, median 4.1, range 7 days–7.2 years,). In 4 cases, age could not be determined, but the attribution to an age group (child/adult) was

possible. Both genders were almost equally represented among adults and children (i.e. in total 41 males (53%), 36 females (46%), and one case with unspecified gender).

3.2 Medications / Medicinal products

An overview of the medications involved in PRE (grouped according to their ATC classification) is presented in Table 1. In 90% of the cases only one medication was administered. Iodinated x-ray contrast media (9 cases, 11.5%) were most frequently involved, followed by iron infusions (7 cases, 9.0%), and phenytoin (4 cases, 5.1%). Disinfectants were the only dermatologicals applied by the wrong route in the study population. Other substances included hydrochloric acid (used for correction of metabolic alkalosis), methanol (0.05ml inadvertently administered during scintigraphy), hydrogen peroxide (erroneously administered during local anesthesia), phenol (used as caustic agent for nail extraction), sodium hydrogencarbonate (used inadvertently instead of lidocaine for local anesthesia), and ethylenediamine-tetracetic acid (EDTA; reflux of blood into a vein from an EDTA-containing blood collection tube).

3.3 Severity and routes of administration

Most patients had mild symptoms or were asymptomatic (Table 2). Severe symptoms were recorded in 6 cases (7.7%) (Table 3), and no fatal outcome was reported. In 40 cases (51.3%) the route was paravenous. Among these, 5 (12.5%) were asymptomatic, 31 (77.5%) showed mild, and 3 (7.5%) moderate or severe symptoms. In one case severity could not be determined definitively because information about clinical course was incomplete. Inadvertent intravenous administration occurred in 26 cases (33%). In 14 (53.8%) of these, patients remained asymptomatic, whereas 5 (19.2%) patients showed mild and 7 (27%) moderate or severe symptoms. Severe symptoms were observed in one, and mild in 5 of the 6

inadvertent subcutaneous administration cases. No symptoms were reported in the 2 inadvertent intramuscular application cases, and in the one with a combined intramuscular and perineural administration. Inadvertent intra-arterial applications resulted in severe symptoms in one case and in mild in the other. Moderate symptoms occurred after extravasation from a Port-A-Cath into the pleural space.

3.4 Symptoms, signs, and outcomes

Symptoms and signs observed after paravenous or subcutaneous incorrect route administrations consisted mainly of minor local discomfort, e.g. swelling (25 cases), pain (14), redness (12), burning (3), and hematoma formation (3). This also applies to the cases of paravenous iron administration, in which symptoms like transient swelling (5 cases), hematoma formation (3), pain (2), and redness (1) were recorded. In cases of inadvertent intravenous administration, patients were either asymptomatic (14 cases) or showed moderate to severe systemic reactions (7) such as tachycardia, hypertension, and ischemic alterations of the ECG after an incorrect administration of epinephrine, or tachycardia and hypotension after the incorrect application of inhalatory solutions containing salbutamol and ipratropium bromide. Among the 6 severe cases in this study (Table 3), the 3 patients with the intravenous and the one with the intra-arterial administration error showed systemic symptoms including coma, convulsions, and circulatory failure. The remaining 2 patients with severe outcome developed local tissue necrosis - one after a paravenous and one after a subcutaneous administration error.

In 58 cases (74%) there were no permanent sequelae. In contrast, in 5 patients (6.4%) symptoms persisted for at least several days and consisted of sensory disturbances in the right upper extremity in one case (extravasation of cefuroxime, morphine, and acetaminophen from a central venous catheter), tingling paraesthesia of the fingertips of one hand in another case

(paravenous administration of an iron containing medication), swelling and erythema in the chest area in a third case (extravasation of paclitaxel from a Port-A-Cath), and local tissue necrosis in two cases requiring surgical intervention (paravasation of phenytoin) and toe amputation (extravasation of phenol), respectively. In 15 cases (19%) data regarding outcome was incomplete.

3.5 Treatments

In most symptomatic cases local unspecific treatment was performed, i.e. cooling (10 cases, 12.8%), immobilization and/or elevated positioning (9 cases, 11.5%), application of a heparin or cortisone containing cream (5 cases, 6.4%), or compression dressings (3 cases, 3.8%). Oral antibiotics were administered in the case of subcutaneous phenol injection with subsequent toe necrosis, and in a case of iron paravasation. Intravenous antibiotics were given prophylactically in an immunosuppressed patient after the erroneous i.v. administration of an oral methadone solution. In the case of inadvertent i.v. application of polyhexanide, hemodialysis was performed in order to enhance removal of the substance according to the literature [19]. In the case of extravasation of vincristine from a Port-A-Cath into the pleural space, pleural lavage was performed with good results.

3.6 Setting, origin of enquiries, and involved hospital departments

In 69 cases (88%) enquiries originated from hospital doctors, the remaining 9 (12%) were from physicians in private practices. The following hospital departments were mainly involved: internal medicine (21 cases, 27.0%), surgery (9, 11.5%), pediatrics (7, 9%), and oncology (4, 5.1%). Eleven (16%) of the hospital cases occurred in emergency departments and 6 (7.7%) in intensive care units. In 10 (21%) cases the department was not reported.

3.7 Daytime and weekday of occurrence

Analysis of PRE in relation to daytime revealed that these events occurred during the whole day, including night-time. A clear peak at a certain daytime was not observed, although cases were rarer during the night. Inadvertent intravenous applications appeared to happen mainly during the morning and around midday, whereas paravasations seemed to occur more frequently in the afternoon and evening. Among the 54 cases in which the exposition time was known (and not only the time of call), 44 enquiries (82%) occurred within 3 hours of the event. No specific relationship between administration errors and day of the week or month was observed.

4. Discussion

Enquiries to our centre concerning administration of medicines and other medicinal products by an incorrect parenteral route were rare, and this is in accordance with previous reports from other PCs, although settings were comparable to a limited extent. Actually, two studies from Germany (only intravenous wrong route) found a frequency of 0.03% [9] and 0.01% [10], respectively, a Finnish study (erroneous route in general) of 0.04% [20], and an Irish study (erroneous route in general) of 0.5% [21]. Nevertheless, a detailed analysis is important and appropriate since every case may deliver new insights into the circumstances of occurrence, resulting symptoms, treatment options, and outcomes, and therefore enable the identification of at-risk situations, with the subsequent possibility to implement effective prevention strategies. Moreover, since experimental study designs would be unethical in this context, and since evidence is scarce for most recommended treatments, such analyses may provide significant information to improve clinical case management.

The follow-up rate of the cases in this study was remarkably high compared to previous analyses [9,10], despite the potential reluctance of health care professionals to report such events, and this may have improved the completeness and overall quality of our data.

In spite of the perceived risk of serious outcomes [9-11], most cases in this study showed a benign clinical course, which is compatible with the results obtained by Deters et al. when analyzing intravenous administration errors [10]. Nevertheless, it is important to recognize that the consequences of incorrect route administration errors are influenced by several factors, such as the specific application route, the amount administered and the characteristics of involved medications, and – if applicable – the duration of tissue exposure [22].

Although the majority of exposures concerned the paravenous route, severe cases were mainly observed after erroneous intravenous administration possibly due to the rapid achievement of high serum concentrations with subsequent systemic effects. A severe outcome seems also plausible after inadvertent intra-arterial administration. Unfortunately, there were not enough cases in this study to substantiate this hypothesis.

The medicines most commonly involved in the study population (x-ray contrast media and iron containing products), differ considerably from the ones identified in the studies by Deters et al. [9,10] (antipsychotics, antihistamines for systemic use, and adrenergics for systemic use in the first study, and antipsychotics, antiseptics/disinfectants, and antihistamines for systemic use in the second, respectively). Remarkable differences are also evident in comparison to a study on wrong route administrations in five Brazilian hospitals [23], where cardiovascular agents, followed by medications acting on the nervous system and the digestive tract and metabolism, respectively, were most commonly involved. Different inclusion criteria may explain the observed differences. Actually, the first two studies focused on medication errors by the intravenous route and also analyzed overdose cases, whereas the last one also included

administration errors by the enteral route. Furthermore, the nature of cases in our study population is subject to selected reporting, which may also explain such differences.

In our study, all PREs involving contrast media had a benign course without sequelae, and this is in line with the findings of Sbitany et al. [24] and Wang et al. [25]. This is probably due to the progressively increased use of low-osmolality, non-ionic contrast media, which do not cause serious injuries in case of extravasation [26]. Regarding the second most commonly involved medication, i.e. iron containing products, information concerning extravasation is scarce in the literature. The product information indicates that in case of paravenous application, a brown discoloration of the skin at the injection site and a local irritation may occur. This is in contrast to our findings, where patients showed symptoms and signs such as swelling, pain, and redness. Unexpectedly, only a few cases of extravasation of oncologic medications were reported to our centre. This could be explained by the fact that specialized nursing and medical staff in oncology units is familiar with these situations, which have been extensively discussed in the literature [12,13,27,28].

In most of our cases, symptomatic treatment was sufficient for both local and systemic reactions. Specific treatments - e.g. hemodialysis, surgical debridement - were required only in a few cases. No specific antidote treatment was needed except for one case in which naloxone was administered (Table 3, case 1). Unfortunately, a more detailed analysis of treatment approaches and their efficacy was not possible due to the limited number of cases in this study.

Most enquiries to our centre were from hospitals and only a few from private practices. Among the former institutions, PREs were relatively rarely reported from emergency departments and intensive care units, which appears surprising considering the stressful working conditions in these units, and the complexity of patients with multiple comorbidities and pharmacological treatments. This observation might be explained by the special training

of nursing and medical staff in these units [29], and, possibly, by the more standardized algorithm-based approach with a frequent use of safety checklists in the critical care setting. Accordingly, Kane-Gill [29] observed that administration errors occurred mainly on general wards, whereas on intensive care units prescribing errors predominated. However we acknowledge that the issue of the frequency of medical errors in the critical care setting is controversially discussed in medical literature [30,31] and our findings might also be influenced by other factors such as underreporting as a consequence of fear of punitive measures [32,33]. In our study, most administration errors occurred on the wards, where work under time pressure due to shortage of personnel and heavy workload are recognized risk factors [34]. Although this has not been specifically addressed in our study, a standardized approach to administration of medications with a more frequent use of safety checklists seems reasonable and should be recommended for all levels of care.

The interpretation of our findings is limited by the retrospective nature of the study design and by the low number and heterogeneity of the cases available for analysis. This implies that detailed information that may be relevant might not have been recorded at the time of the initial call. In addition, PC's data are subject to reporting bias, as it has been previously described [35]. Underreporting may particularly be an issue when studying medication errors, because the fear of disciplinary actions and legal consequences may limit reporting of such cases. On the other hand, the perceived risk of serious outcomes could prompt health care professionals to ask for advice, and this may be especially true for cases in which severe symptoms and signs have developed, potentially biasing the results towards higher percentage of severe cases.

5. Conclusions

In conclusion, enquiries to our centre concerning administration of medicines or medicinal products by an incorrect parenteral route were rare, and mainly involved iodinated x-ray contrast media and iron containing products. Most events occurred in adults and showed a benign clinical course with complete recovery. Although the majority of exposures concerned the paravenous route, the occasional severe cases were observed mainly after inadvertent intravenous administration. In most cases, enquiries originated from hospital doctors of the following departments: internal medicine, surgery, pediatrics, and oncology.

We recommend particular attention should be paid when administering iron infusions and contrast media. In case of erroneous application of a medication by an intravenous route, close monitoring of the patient is advised. The implementation of preventive strategies seems advisable, especially on internal medicine wards.

To investigate the problem of medication wrong route administration in more detail, a prospective study, which would allow collecting data in a more structured way and therefore provide more complete information about the cases, is planned at our centre.

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List of abbreviations

STIC	Swiss Toxicological Information Centre
PRE	Parenteral Route Error
ATC	Anatomic Therapeutic Chemical
PSS	Poisoning Severity Score

Table 1. Groups of medications and medicinal products involved in parenteral wrong route application cases in relation to the administration route

Medication group / Medicinal products (ATC code in parentheses)	Para- venous	Intra- venous	Subcuta- neous	Intra- arterial	Intra- muscular	Other	Total
Nervous system (N)	6	9	1	1			17 (21.8%)
Blood and blood-forming organs (B)	10	1	1		1		13 (16.6%)
Various (V) (mainly contrast media)	9	2					11 (14.1%)
Anti-infectives for systemic use (J)	8			1			9 (11.5%)
Medicinal products (e.g. alcohol, soap)	1	2	3				6 (7.7%)
Anti-neoplastic and immuno-modulating agents (L)	3					1	4 (5.1%)
Musculo-skeletal system (M)	3				1		4 (5.1%)
Respiratory system (R)		4					4 (5.1%)
Alimentary tract and metabolism (A)		3					3 (3.9%)
Dermatologicals (D)		1	1			1	3 (3.9%)
Systemic hormonal preparations (H)		3					3 (3.9%)
Cardiovascular system (C)		1					1 (1.3%)
Total	40	26	6	2	2	2	78 (100%)

Table 2. Severity of cases of parenteral wrong route administration in relation to patient characteristics (percentages in parentheses)

Age	Gender	Severity of symptoms					Total (%)
		None	Minor	Moderate	Severe	Not classifiable	
Adults	Male	12	17	3	2	1	35 (44.9)
	Female	8	18	2	4	0	32 (41)
	Unknown	0	1	0	0	0	1 (1.3)
	Subtotal	20	36	5	6	1	68 (87.2)
Children (≤ 16 y/o)	Male	2	4	0	0	0	6 (7.7)
	Female	0	2	2	0	0	4 (5.1)
	Subtotal	2	6	2	0	0	10 (12.8)
Total (%)		22 (28)	42 (54)	7 (9)	6 (7.7)	1 (1.3)	78 (100)